

110TH CONGRESS
2D SESSION

H. R. _____

To amend the Public Health Service Act to promote the adoption of health
information technology, and for other purposes

IN THE HOUSE OF REPRESENTATIVES

M____ introduced the following bill; which was referred to the
Committee on _____

A BILL

To amend the Public Health Service Act to promote the
adoption of health information technology, and for other
purposes

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “**[to be provided of 2008]**”.

6 (b) TABLE OF CONTENTS.—The table of contents of
7 this Act is as follows:

Sec. 1. Short title; table of contents.

TITLE I—HEALTH INFORMATION TECHNOLOGY

Subtitle A—Promotion of Health Information Technology

2

PART 1—IMPROVING HEALTH CARE QUALITY, SAFETY, AND EFFICIENCY

Sec. 101. ONCHIT; standards development and adoption; health information technology resource center.

“TITLE XXX—HEALTH INFORMATION TECHNOLOGY AND
QUALITY

“Sec. 3000. Definitions.

“Subtitle A—Promotion of Health Information Technology

“Sec. 3001. Office of the National Coordinator for Health Information Technology.

“Sec. 3002. HIT Policy Committee.

“Sec. 3003. HIT Standards Committee.

“Sec. 3004. Process for adoption of endorsed recommendations.

“Sec. 3005. Application and use of adopted standards and implementation specifications by Federal agencies.

“Sec. 3006. Voluntary application and use of adopted standards and implementation specifications by private entities.

“Sec. 3007. Health Information Technology Resource Center.

Sec. 102. Transitions.

PART 2—APPLICATION AND USE OF ADOPTED HEALTH INFORMATION
TECHNOLOGY STANDARDS; REPORTS

Sec. 111. Coordination of Federal activities with adopted standards and implementation specifications.

Sec. 112. Application to private entities.

Sec. 113. Reports.

Subtitle B—Incentives for the Use of Health Information Technology

Sec. 121. Grant, loan, and demonstration programs.

“Subtitle B—Incentives for the Use of Health Information Technology

“Sec. 3011. Grants and loans to facilitate the widespread adoption of qualified health information technology.

“Sec. 3012. Demonstration program to integrate information technology into clinical education.

TITLE II—TESTING OF HEALTH INFORMATION TECHNOLOGY

Sec. 201. National Institute for Standards and Technology testing.

Sec. 202. Research and development programs.

TITLE III—PRIVACY AND SECURITY PROVISIONS

Sec. 300. Definitions.

Subtitle A—Security Provisions

Sec. 301. Application of security provisions and penalties to business associates of covered entities; annual guidance on security provisions.

Sec. 302. Notification in the case of breach.

Sec. 303. Education on Health Information Privacy and report on compliance.

Subtitle B—Improved Privacy Provisions

- Sec. 311. Application of penalties to business associates of covered entities for violations of privacy contract requirements.
- Sec. 312. Requested restrictions on certain disclosures of health information; accounting of certain protected health information disclosures.
- Sec. 313. Conditions on certain contacts as part of health care operations.
- Sec. 314. Study on application of privacy and security requirements to vendors of personal health records.
- Sec. 315. Temporary breach notification requirement for vendors of personal health records.
- Sec. 316. Business associate contracts required for certain entities.
- Sec. 317. Guidance on implementation specification to de-identify protected health information.
- Sec. 318. GAO report on treatment disclosures.

Subtitle C—Relationship to Other Laws; Effective Date

- Sec. 321. Relationship to other laws.
- Sec. 322. Effective date.

1 **TITLE I—HEALTH INFORMATION**

2 **TECHNOLOGY**

3 **Subtitle A—Promotion of Health**

4 **Information Technology**

5 **PART 1—IMPROVING HEALTH CARE QUALITY,**

6 **SAFETY, AND EFFICIENCY**

7 **SEC. 101. ONCHIT; STANDARDS DEVELOPMENT AND ADOP-**

8 **TION; HEALTH INFORMATION TECHNOLOGY**

9 **RESOURCE CENTER.**

10 (a) IN GENERAL.—The Public Health Service Act

11 (42 U.S.C. 201 et seq.) is amended by adding at the end

12 the following:

1 **“TITLE XXX—HEALTH INFORMA-**
2 **TION TECHNOLOGY AND**
3 **QUALITY**

4 **“SEC. 3000. DEFINITIONS.**

5 “In this title:

6 “(1) ENTERPRISE INTEGRATION.—The term
7 ‘enterprise integration’ means the electronic linkage
8 of health care providers, health insurance plans, the
9 government, and other interested parties, to enable
10 the electronic exchange and use of health informa-
11 tion among all the components in the health care in-
12 frastructure, and such term includes related applica-
13 tion protocols and other related standards.

14 “(2) HEALTH CARE PROVIDER.—The term
15 ‘health care provider’ means a hospital, skilled nurs-
16 ing facility, home health entity, health care clinic,
17 Federally qualified health center, group practice (as
18 defined in section 1877(h)(4) of the Social Security
19 Act), a pharmacist, a pharmacy, a laboratory, a phy-
20 sician (as defined in section 1861(r) of the Social
21 Security Act), a practitioner (as described in section
22 1842(b)(18)(C) of the Social Security Act), a pro-
23 vider operated by, or under contract with, the Indian
24 Health Service or by an Indian tribe (as defined in
25 the Indian Self-Determination and Education Assist-

1 ance Act), tribal organization, or urban Indian orga-
2 nization (as defined in section 4 of the Indian
3 Health Care Improvement Act)), a rural health clin-
4 ic, and any other category of facility or clinician de-
5 termined appropriate by the Secretary.

6 “(3) HEALTH INFORMATION.—The term ‘health
7 information’ has the meaning given such term in
8 section 1171(4) of the Social Security Act.

9 “(4) HEALTH INFORMATION TECHNOLOGY.—
10 The term ‘health information technology’ means
11 hardware, software, license, right, intellectual prop-
12 erty, equipment, or other information technology (in-
13 cluding new versions, upgrades, and connectivity)
14 designed or provided primarily for the electronic cre-
15 ation, maintenance, or exchange of health informa-
16 tion to better coordinate care or improve health care
17 quality, efficiency, or research.

18 “(5) HEALTH INSURANCE PLAN.—The term
19 ‘health insurance plan’ means—

20 “(A) a health insurance issuer (as defined
21 in section 2791(b)(2)), including a a health
22 maintenance organization (as defined in section
23 2791(b)(3)); and

24 “(B) a group health plan (as defined in
25 section 2791(a)(1)).

1 “(6) HIT POLICY COMMITTEE.—The term ‘HIT
2 Policy Committee’ means such Committee estab-
3 lished under section 3002(a).

4 “(7) HIT STANDARDS COMMITTEE.—The term
5 ‘HIT Standards Committee’ means such Committee
6 established under section 3003(a).

7 “(8) INDIVIDUALLY IDENTIFIABLE HEALTH IN-
8 FORMATION.—The term ‘individually identifiable
9 health information’ has the meaning given such term
10 in section 1171(6) of the Social Security Act.

11 “(9) LABORATORY.—The term ‘laboratory’ has
12 the meaning given that term in section 353(a).

13 “(10) NATIONAL COORDINATOR.—The term
14 ‘National Coordinator’ means the head of the Office
15 of the National Coordinator for Health Information
16 Technology established under section 3001(a).

17 “(11) PHARMACIST.—The term ‘pharmacist’
18 has the meaning given that term in section 804(2)
19 of the Federal Food, Drug, and Cosmetic Act.

20 “(12) STATE.—The term ‘State’ means each of
21 the several States, the District of Columbia, Puerto
22 Rico, the Virgin Islands, Guam, American Samoa,
23 and the Northern Mariana Islands.

1 **“Subtitle A—Promotion of Health**
2 **Information Technology**

3 **“SEC. 3001. OFFICE OF THE NATIONAL COORDINATOR FOR**
4 **HEALTH INFORMATION TECHNOLOGY.**

5 “(a) ESTABLISHMENT.—There is established within
6 the Department of Health and Human Services an Office
7 of the National Coordinator for Health Information Tech-
8 nology (referred to in this section as the ‘Office’). The Of-
9 fice shall be headed by a National Coordinator who shall
10 be appointed by the Secretary and shall report directly to
11 the Secretary.

12 “(b) PURPOSE.—The National Coordinator shall per-
13 form the duties under subsection (c) in a manner con-
14 sistent with the development of a nationwide interoperable
15 health information technology infrastructure that—

16 “(1) ensures that each patient’s health informa-
17 tion is secure and protected, in accordance with ap-
18 plicable law;

19 “(2) improves health care quality, reduces med-
20 ical errors, and advances the delivery of patient-cen-
21 tered medical care;

22 “(3) reduces health care costs resulting from
23 inefficiency, medical errors, inappropriate care, du-
24 plicative care, and incomplete information;

1 “(4) ensures that appropriate information to
2 help guide medical decisions is available at the time
3 and place of care;

4 “(5) improves the coordination of care and in-
5 formation among hospitals, laboratories, physician
6 offices, and other entities through an effective infra-
7 structure for the secure and authorized exchange of
8 health care information;

9 “(6) improves public health reporting and facili-
10 tates the early identification and rapid response to
11 public health threats and emergencies, including bio-
12 terror events and infectious disease outbreaks;

13 “(7) facilitates health research and health care
14 quality;

15 “(8) promotes prevention of chronic diseases;
16 and

17 “(9) promotes a more effective marketplace,
18 greater competition, greater systems analysis, in-
19 creased consumer choice, and improved outcomes in
20 health care services.

21 “(c) DUTIES OF THE NATIONAL COORDINATOR.—

22 “(1) STANDARDS.—The National Coordinator
23 shall review and determine whether to endorse each
24 standard, implementation specification, and certifi-
25 cation criterion for the electronic exchange and use

1 of health information that is recommended by the
2 HIT Standards Committee under section 3003 for
3 purposes of adoption under section 3004(b). The Co-
4 ordinator shall make such determination, and report
5 to the Secretary such determination, not later than
6 90 days after the date the recommendation is re-
7 ceived by the Coordinator.

8 “(2) HIT POLICY COORDINATION.—The Na-
9 tional Coordinator shall coordinate health informa-
10 tion technology policy and programs of the Depart-
11 ment with those of other relevant executive branch
12 agencies with a goal of avoiding duplication of ef-
13 forts and of helping to ensure that each agency un-
14 dertakes health information technology activities pri-
15 marily within the areas of its greatest expertise and
16 technical capability.

17 “(3) STRATEGIC PLAN.—

18 “(A) IN GENERAL.—The National Coordi-
19 nator shall, in consultation with other appro-
20 priate Federal agencies (including the National
21 Institute of Standards and Technology), develop
22 and update a strategic plan with specific objec-
23 tives, milestones, and metrics for the following:

1 “(i) The electronic exchange and use
2 of health information and the enterprise
3 integration of such information.

4 “(ii) The utilization of an electronic
5 health record for each person in the United
6 States by 2014.

7 “(iii) The incorporation of privacy
8 considerations in the electronic exchange
9 and use of health information.

10 “(iv) Ensuring security methods to
11 ensure appropriate authorization, elec-
12 tronic authentication, and encryption of
13 health information.

14 “(v) Specifying a framework for co-
15 ordination and flow of recommendations
16 and policies under this subtitle among the
17 Secretary, the National Coordinator, the
18 HIT Policy Committee, the HIT Standards
19 Committee, and other health information
20 exchanges and other relevant entities.

21 “(vi) Methods to foster the public un-
22 derstanding of health information tech-
23 nology.

24 “(vii) Strategies to enhance the use of
25 health information technology in improving

1 the quality of health care and reducing
2 medical errors.

3 “(B) COLLABORATION.—The strategic
4 plan shall be developed and updated through
5 collaboration of public and private interests.

6 “(C) MEASURABLE OUTCOME GOALS.—
7 The strategic plan shall include measurable out-
8 come goals.

9 “(D) PUBLICATION.—The National Coor-
10 dinator shall publish the strategic plan, includ-
11 ing all updates.

12 “(4) WEBSITE.—The National Coordinator
13 shall maintain and frequently update an Internet
14 website on which there is posted information that in-
15 cludes the following:

16 “(A) The schedule developed by the HIT
17 Standards Committee under section 3003(b)(3).

18 “(B) The recommendations of the HIT
19 Policy Committee under section 3002.

20 “(C) Recommendations of the HIT Stand-
21 ards Committee under section 3003.

22 “(D) Sources of grant funds and technical
23 assistance that are available to facilitate the
24 purchase of, or enhance the utilization of,
25 health information technology systems.

1 “(5) IMPLEMENTATION REPORT.—The National
2 Coordinator shall prepare a report that identifies
3 lessons learned from major public and private health
4 care systems in their implementation of health infor-
5 mation technology systems, including information on
6 whether the systems and practices developed by such
7 systems may be applicable to and usable in whole or
8 in part by other health care providers.

9 “(6) ASSESSMENT OF IMPACT OF HIT ON COM-
10 MUNITIES WITH HEALTH DISPARITIES AND UNIN-
11 SURED, UNDERINSURED, AND MEDICALLY UNDER-
12 SERVED AREAS.—The National Coordinator shall as-
13 sess and publish the impact of health information
14 technology in communities with health disparities
15 and in areas that serve uninsured, underinsured,
16 and medically underserved individuals (including
17 urban and rural areas) and identify practices to in-
18 crease the adoption of such technology by health
19 care providers in such communities.

20 “(7) EVALUATION OF BENEFITS AND COSTS OF
21 INTEROPERABILITY.—The National Coordinator
22 shall evaluate and publish evidence on the benefits
23 and costs of interoperable health information tech-
24 nology and assess to whom these benefits and costs
25 accrue.

1 “(8) RESOURCE REQUIREMENTS.—The Na-
2 tional Coordinator shall estimate and publish re-
3 sources required annually to reach the goal of utili-
4 zation of an electronic health record for each person
5 in the United States by 2014, including the required
6 level of Federal funding, expectations for regional,
7 State, and private investment, and the expected con-
8 tributions by volunteers to activities for the utiliza-
9 tion of such records.

10 “(9) CERTIFICATION.—

11 “(A) IN GENERAL.—The National Coordi-
12 nator, in consultation with the Director of the
13 National Institute of Standards and Tech-
14 nology, shall develop a program (either directly
15 or by contract) for the voluntary certification of
16 health information technology as being in com-
17 pliance with applicable certification criteria
18 adopted under this subtitle. Such program shall
19 include testing of the technology in accordance
20 with section 201(b) of **[*short title*]**.

21 “(B) CERTIFICATION CRITERIA DE-
22 SCRIBED.—In this title, the term ‘certification
23 criteria’ means, with respect to standards and
24 implementation specifications for health infor-
25 mation technology, criteria to establish that the

1 technology meets such standards and implemen-
2 tation specifications.

3 “(d) DETAIL OF FEDERAL EMPLOYEES.—

4 “(1) IN GENERAL.—Upon the request of the
5 National Coordinator, the head of any Federal agen-
6 cy is authorized to detail, with or without reimburse-
7 ment from the Office, any of the personnel of such
8 agency to the Office to assist it in carrying out its
9 duties under this section.

10 “(2) EFFECT OF DETAIL.—Any detail of per-
11 sonnel under paragraph (1) shall—

12 “(A) not interrupt or otherwise affect the
13 civil service status or privileges of the Federal
14 employee; and

15 “(B) be in addition to any other staff of
16 the Department employed by the National Co-
17 ordinator.

18 “(3) ACCEPTANCE OF DETAILEES.—Notwith-
19 standing any other provision of law, the Office may
20 accept detailed personnel from other Federal agen-
21 cies without regard to whether the agency described
22 under paragraph (1) is reimbursed.

23 “(e) AUTHORIZATION OF APPROPRIATIONS.—There
24 are authorized to be appropriated to carry out this section

1 such sums as may be necessary for each of the fiscal years
2 2009 through 2013.

3 **“SEC. 3002. HIT POLICY COMMITTEE.**

4 “(a) ESTABLISHMENT.—There is established a HIT
5 Policy Committee to make policy recommendations to the
6 National Coordinator relating to the implementation of a
7 nationwide health information technology infrastructure,
8 including implementation of the strategic plan described
9 in section 3001(c)(3).

10 “(b) DUTIES.—

11 “(1) RECOMMENDATIONS ON HEALTH INFOR-
12 MATION TECHNOLOGY INFRASTRUCTURE.—Not later
13 than 1 year after the date of the enactment of this
14 title, the HIT Policy Committee shall recommend a
15 policy framework for the development and adoption
16 of a nationwide health information technology infra-
17 structure that permits the electronic exchange and
18 use of health information as is consistent with the
19 strategic plan under section 3001(c)(3) and that in-
20 cludes the recommendations under paragraph (2).
21 Annually thereafter the Committee shall update such
22 recommendations and make new recommendations
23 as appropriate.

24 “(2) SPECIFIC AREAS OF STANDARD DEVELOP-
25 MENT.—

1 “(A) IN GENERAL.—The HIT Policy Com-
2 mittee shall recommend the areas in which
3 standards, implementation specifications, and
4 certification criteria are needed for the elec-
5 tronic exchange and use of health information
6 for purposes of adoption under section 3004(b)
7 and shall recommend an order of priority for
8 the development of such standards, specifica-
9 tions, and criteria among the areas so rec-
10 ommended. Such standards and implementation
11 specifications shall include named standards,
12 architectures, and software schemes for the au-
13 thentication and security of health information
14 and other information as needed to ensure the
15 reproducible development of common solutions
16 across disparate entities.

17 “(B) AREAS REQUIRED FOR CONSIDER-
18 ATION.—In making recommendations under
19 subparagraph (A), the HIT Policy Committee
20 shall consider at least the following areas:

21 “(i) Technologies that protect the pri-
22 vacy of health information and promote se-
23 curity, in accordance with applicable law,
24 including for the protection from disclosure
25 of specific individually identifiable health

1 information, as requested by a patient and
2 agreed to by the provider involved, and for
3 the use and disclosure of limited data sets
4 (as defined for purposes of regulations pro-
5 mulgated under section 264(e) of the
6 Health Insurance Portability and Account-
7 ability Act of 1996) of such information.

8 “(ii) A nationwide interoperable
9 health information technology infrastruc-
10 ture that permits the electronic exchange
11 and use of health information.

12 “(iii) The utilization of an electronic
13 health record for each person in the United
14 States by 2014.

15 “(C) OTHER AREAS FOR CONSIDER-
16 ATION.—In making recommendations under
17 subparagraph (A), the HIT Policy Committee
18 may consider the following additional areas:

19 “(i) The appropriate uses of a nation-
20 wide health information infrastructure, in-
21 cluding for purposes of—

22 “(I) the collection of quality data
23 and public reporting;

24 “(II) biosurveillance and public
25 health;

1 “(III) medical and clinical re-
2 search; and

3 “(IV) drug safety.

4 “(ii) Self-service technologies that fa-
5 cilitate the use and exchange of patient in-
6 formation and reduce wait times.

7 “(iii) Telemedicine technologies, in
8 order to reduce travel requirements for pa-
9 tients in remote areas.

10 “(iv) Technologies that facilitate home
11 health care and the monitoring of patients
12 recuperating at home.

13 “(v) Technologies that help reduce
14 medical errors.

15 “(vi) Technologies that facilitate the
16 continuity of care among health settings.

17 “(vii) Any other technology that the
18 HIT Policy Committee finds to be among
19 the technologies with the greatest potential
20 to improve the quality and efficiency of
21 health care.

22 “(3) FORUM.—The HIT Policy Committee shall
23 serve as a forum for broad stakeholder input with
24 specific expertise in policies relating to the matters
25 described in paragraphs (1) and (2).

1 “(4) WEBSITE.—The HIT Policy Committee
2 shall develop and maintain an Internet website on
3 which there is posted information that includes the
4 following:

5 “(A) Established governance rules.

6 “(B) A business plan.

7 “(C) Meeting notices at least 14 days prior
8 to each meeting.

9 “(D) Meeting agendas at least 7 days prior
10 to each meeting.

11 “(E) Meeting materials at least 3 days
12 prior to each meeting.

13 “(c) MEMBERSHIP.—

14 “(1) IN GENERAL.—The HIT Policy Committee
15 shall be composed of members to be appointed as
16 follows:

17 “(A) 3 members shall be appointed by the
18 Secretary, 1 of whom shall be appointed to rep-
19 resent the Department of Health and Human
20 Services.

21 “(B) 1 member shall be appointed by the
22 majority leader of the Senate.

23 “(C) 1 member shall be appointed by the
24 minority leader of the Senate.

1 “(D) 1 member shall be appointed by the
2 Speaker of the House of Representatives.

3 “(E) 1 member shall be appointed by the
4 minority leader of the House of Representa-
5 tives.

6 “(F) Such other members as shall be ap-
7 pointed by the President as representatives of
8 other relevant Federal agencies.

9 “(G) 9 members shall be appointed by the
10 Comptroller General of the United States of
11 whom—

12 “(i) 1 member shall be an advocate
13 for patients or consumers;

14 “(ii) 1 member shall represent health
15 care providers;

16 “(iii) 1 member shall be from a labor
17 organization representing health care
18 workers;

19 “(iv) 1 member shall have expertise in
20 privacy and security;

21 “(v) 1 member shall have expertise in
22 improving the health of vulnerable popu-
23 lations;

24 “(vi) 1 member shall represent health
25 plans or other third-party payers;

1 “(vii) 1 member shall represent infor-
2 mation technology vendors;

3 “(viii) 1 member shall represent pur-
4 chasers or employers; and

5 “(ix) 1 member shall have expertise in
6 health care quality measurement and re-
7 porting.

8 “(2) NATIONAL COORDINATOR.—The National
9 Coordinator shall be a member of the HIT Policy
10 Committee and act as a liaison among the HIT Pol-
11 icy Committee, the HIT Standards Committee, and
12 the Federal Government.

13 “(3) CHAIRPERSON AND VICE CHAIRPERSON.—
14 The HIT Policy Committee shall designate 1 mem-
15 ber to serve as the chairperson and 1 member to
16 serve as the vice chairperson of the HIT Policy
17 Committee.

18 “(4) PARTICIPATION.—The members of the
19 HIT Policy Committee appointed under paragraph
20 (1) shall represent a balance among various sectors
21 of the health care system so that no single sector
22 unduly influences the recommendations of such
23 Committee.

24 “(5) TERMS.—

1 “(A) IN GENERAL.—The terms of mem-
2 bers of the HIT Policy Committee appointed
3 under paragraph (1) shall be 3 years except
4 that the Comptroller General of the United
5 States shall designate staggered terms for the
6 members first appointed under paragraph
7 (1)(G).

8 “(B) VACANCIES.—Any member appointed
9 to fill a vacancy in the membership of the HIT
10 Policy Committee that occurs prior to the expi-
11 ration of the term for which the member’s pred-
12 ecessor was appointed shall be appointed only
13 for the remainder of that term. A member may
14 serve after the expiration of that member’s
15 term until a successor has been appointed. A
16 vacancy in the HIT Policy Committee shall be
17 filled in the manner in which the original ap-
18 pointment was made.

19 “(6) OUTSIDE INVOLVEMENT.—The HIT Policy
20 Committee shall ensure an adequate opportunity for
21 the participation of outside advisors, including indi-
22 viduals with expertise in the development of policies
23 for the electronic exchange and use of health infor-
24 mation, including in the areas of health information
25 privacy and security.

1 “(7) QUORUM.—Ten members of the HIT Pol-
2 icy Committee shall constitute a quorum for pur-
3 poses of voting, but a lesser number of members
4 may meet and hold hearings.

5 “(d) APPLICATION OF FACCA.—The Federal Advisory
6 Committee Act (5 U.S.C. App.), other than section 14 of
7 such Act, shall apply to the HIT Policy Committee.

8 “(e) PUBLICATION.—The Secretary shall provide for
9 publication in the Federal Register and the posting on the
10 Internet website of the Office of the National Coordinator
11 for Health Information Technology of all policy rec-
12 ommendations made by the HIT Policy Committee under
13 this section.

14 “(f) AUTHORIZATION OF APPROPRIATIONS.—There
15 are authorized to be appropriated to carry out this section,
16 such sums as may be necessary for each of the fiscal years
17 2009 through 2013.

18 **“SEC. 3003. HIT STANDARDS COMMITTEE.**

19 “(a) ESTABLISHMENT.—There is established a com-
20 mittee to be known as the HIT Standards Committee to
21 recommend to the National Coordinator standards, imple-
22 mentation specifications, and certification criteria for the
23 electronic exchange and use of health information for pur-
24 poses of adoption under section 3004(b), consistent with

1 the implementation of the strategic plan described in sec-
2 tion 3001(c)(3).

3 “(b) DUTIES.—

4 “(1) STANDARD DEVELOPMENT.—

5 “(A) IN GENERAL.—Beginning not later
6 than 1 year after the date of the enactment of
7 this title, the HIT Standards Committee shall
8 develop and recommend to the National Coordi-
9 nator standards, implementation specifications,
10 and certification criteria described in subsection
11 (a). Annually thereafter the Committee shall
12 update such recommendations and make new
13 recommendations as appropriate, including in
14 response to a notification sent under section
15 3004(b)(2). Such recommendations shall be
16 consistent with the latest recommendations
17 made by the HIT Policy Committee.

18 “(B) PILOT TESTING OF STANDARDS AND
19 IMPLEMENTATION SPECIFICATIONS.—In the de-
20 velopment of standards and implementation
21 specifications, the HIT Standards Committee,
22 as appropriate, shall provide for the testing of
23 such standards and specifications by the Na-
24 tional Institute for Standards and Technology
25 under title II of the *short title*.

1 “(C) CONSISTENCY.—The standards, im-
2 plementation specifications, and certification
3 criteria described in this subsection shall be
4 consistent with the standards for information
5 transactions and data elements adopted pursu-
6 ant to section 1173 of the Social Security Act.

7 “(2) FORUM.—The HIT Standards Committee
8 shall serve as a forum for the participation of a
9 broad range of stakeholders to provide input on the
10 development of standards, implementation specifica-
11 tions, and certification criteria necessary for the de-
12 velopment and adoption of a nationwide interoper-
13 able health information technology infrastructure.

14 “(3) SCHEDULE.—Not later than 90 days after
15 the date of the enactment of this title, the HIT
16 Standards Committee shall develop a schedule for
17 the assessment of policy recommendations developed
18 by the HIT Policy Committee under section 3002.
19 The HIT Standards Committee shall update such
20 schedule annually. The Secretary shall publish such
21 schedule in the Federal Register.

22 “(4) PUBLIC INPUT.—The HIT Standards
23 Committee shall conduct open public meetings and
24 develop a process to allow for public comment on the
25 schedule described in paragraph (3) and rec-

1 ommendations described in this subsection. Such
2 process shall ensure that such comments will be sub-
3 mitted within 30 days after the date of publication
4 of a recommendation under this subsection.

5 “(5) WEBSITE.—The HIT Standards Com-
6 mittee shall develop and maintain an Internet
7 website on which there is posted information that in-
8 cludes the following:

9 “(A) Established governance rules.

10 “(B) A business plan.

11 “(C) Meeting notices at least 14 days prior
12 to each meeting.

13 “(D) Meeting agendas at least 7 days prior
14 to each meeting.

15 “(E) Meeting materials at least 3 days
16 prior to each meeting.

17 “(6) REQUIREMENT TO INTEGRATE REC-
18 OMMENDATIONS.—In carrying out the activities
19 under this section, the HIT Standards Committee
20 shall integrate the recommendations of the HIT Pol-
21 icy Committee.

22 “(c) MEMBERSHIP.—

23 “(1) APPOINTMENTS.—

1 “(A) IN GENERAL.—The HIT Standards
2 Committee shall be composed of members to be
3 appointed as follows:

4 “(i) 2 members shall be appointed by
5 the Secretary.

6 “(ii) 1 member shall be appointed by
7 the majority leader of the Senate.

8 “(iii) 1 member shall be appointed by
9 the minority leader of the Senate.

10 “(iv) 1 member shall be appointed by
11 the Speaker of the House of Representa-
12 tives.

13 “(v) 1 member shall be appointed by
14 the minority leader of the House of Rep-
15 resentatives.

16 “(vi) 7 members shall be appointed by
17 the Comptroller General of the United
18 States of whom—

19 “(I) 1 member shall be a rep-
20 resentative of consumer or patient or-
21 ganizations;

22 “(II) 1 member shall be a rep-
23 resentative of organizations with ex-
24 pertise in privacy;

1 “(III) 1 member shall be a rep-
2 resentative of organizations with ex-
3 pertise in security;

4 “(IV) 1 member shall be a rep-
5 resentative of health care providers;

6 “(V) 1 member shall be a rep-
7 resentative of health plans or other
8 third party payers;

9 “(VI) 1 member shall be a rep-
10 resentative of information technology
11 vendors; and

12 “(VII) 1 member shall be a rep-
13 resentative of purchasers or employ-
14 ers.

15 “(vii) 1 member shall be from the Na-
16 tional Institute for Standards and Tech-
17 nology.

18 “(B) NATIONAL COORDINATOR.—The Na-
19 tional Coordinator shall be a member of the
20 HIT Standards Committee and act as a liaison
21 among the HIT Standards Committee, the HIT
22 Policy Committee, and the Federal government.

23 “(2) CHAIRPERSON AND VICE CHAIRPERSON.—
24 The HIT Standards Committee shall designate 1

1 member to serve as the chairperson and 1 member
2 to serve as the vice chairperson of the Committee.

3 “(3) BALANCE.—In appointing members under
4 paragraph (1)(A)(vi), the Comptroller General of the
5 United States shall ensure a balance among various
6 sectors of the health care system so that no single
7 sector unduly influences the recommendations of the
8 HIT Standards Committee.

9 “(4) TERMS.—Members appointed under para-
10 graph (1)(A) shall serve for 3-year terms, except
11 that any member appointed to fill a vacancy for an
12 unexpired term shall be appointed for the remainder
13 of such term. A member may serve for not to exceed
14 180 days after the expiration of such member’s term
15 or until a successor has been appointed.

16 “(5) OUTSIDE INVOLVEMENT.—The HIT
17 Standards Committee shall ensure an adequate op-
18 portunity for the participation of outside advisors,
19 including individuals with expertise in the develop-
20 ment of standards for the electronic exchange and
21 use of health information, including in the areas of
22 health information privacy and security.

23 “(d) APPLICATION OF FACA.—The Federal Advisory
24 Committee Act (5 U.S.C. App.), other than section 14,
25 shall apply to the HIT Standards Committee.

1 “(e) PUBLICATION.—The Secretary shall provide for
2 publication in the Federal Register and the posting on the
3 Internet website of the Office of the National Coordinator
4 for Health Information Technology of all recommenda-
5 tions made by the HIT Standards Committee under this
6 section.

7 “(f) AUTHORIZATION OF APPROPRIATIONS.—There
8 are authorized to be appropriated to carry out this section
9 such sums as may be necessary for each of the fiscal years
10 2009 through 2013.

11 **“SEC. 3004. PROCESS FOR ADOPTION OF ENDORSED REC-**
12 **COMMENDATIONS.**

13 “(a) REVIEW OF ENDORSED STANDARDS, SPECI-
14 FICATIONS, AND CRITERIA.—Not later than 90 days after
15 the date of receipt of a standard, implementation speci-
16 fication, or certification criterion endorsed under section
17 3001(c), the Secretary, in consultation with representa-
18 tives of other relevant Federal agencies, shall jointly re-
19 view such standard, specification, or criterion and shall de-
20 termine whether or not to propose adoption of such stand-
21 ard, specification, or criterion.

22 “(b) DETERMINATION TO ADOPT STANDARDS, SPEC-
23 IFICATIONS, AND CRITERIA.—If the Secretary deter-
24 mines—

1 “(1) to propose adoption of such standard,
2 specification, or criterion, the Secretary shall,
3 through a rulemaking process, determine whether or
4 not to adopt such standard, specification, or cri-
5 terion; or

6 “(2) not to propose adoption of such standard,
7 specification, or criterion, the Secretary shall notify
8 the National Coordinator and the HIT Standards
9 Committee in writing of such determination and the
10 reasons for not endorsing such recommendation.

11 “(c) PUBLICATION.—The Secretary shall provide for
12 publication in the Federal Register of all determinations
13 made by the Secretary under subsection (a).

14 **“SEC. 3005. APPLICATION AND USE OF ADOPTED STAND-**
15 **ARDS AND IMPLEMENTATION SPECIFICA-**
16 **TIONS BY FEDERAL AGENCIES.**

17 “For requirements relating to the application and use
18 by Federal agencies of the standards and implementation
19 specifications adopted under section 3004(b), see section
20 111 of the *【short title】*.

21 **“SEC. 3006. VOLUNTARY APPLICATION AND USE OF ADOPT-**
22 **ED STANDARDS AND IMPLEMENTATION**
23 **SPECIFICATIONS BY PRIVATE ENTITIES.**

24 “(a) IN GENERAL.—Except as provided under section
25 112 of the *【short title】*, any standard or implementation

1 specification adopted under section 3004(b) shall be vol-
2 untary with respect to private entities.

3 “(b) RULE OF CONSTRUCTION.—Nothing in this sub-
4 title shall be construed to require that a private entity that
5 enters into a contract with the Federal Government apply
6 or use the standards and implementation specifications
7 adopted under section 3004(b) with respect to activities
8 not related to the contract.

9 **“SEC. 3007. HEALTH INFORMATION TECHNOLOGY RE-**
10 **SOURCE CENTER.**

11 “(a) DEVELOPMENT.—

12 “(1) IN GENERAL.—The National Coordinator
13 shall develop a Health Information Technology Re-
14 source Center to provide technical assistance and de-
15 velop best practices to support and accelerate efforts
16 to adopt, implement, and effectively use interoper-
17 able health information technology in compliance
18 with standards, implementation specifications, and
19 certification criteria adopted under section 3004(b).

20 “(2) PURPOSES.—The purpose of the Center is
21 to—

22 “(A) provide a forum for the exchange of
23 knowledge and experience;

24 “(B) accelerate the transfer of lessons
25 learned from existing public and private sector

1 initiatives, including those currently receiving
2 Federal financial support;

3 “(C) assemble, analyze, and widely dis-
4 seminate evidence and experience related to the
5 adoption, implementation, and effective use of
6 interoperable health information technology;

7 “(D) provide technical assistance for the
8 establishment and evaluation of regional and
9 local health information networks to facilitate
10 the development of interoperability across
11 health care settings and improve the quality of
12 health care;

13 “(E) provide technical assistance for the
14 development and dissemination of solutions to
15 barriers to the exchange of electronic health in-
16 formation; and

17 “(F) conduct other activities identified by
18 the States, local or regional health information
19 networks, or health care stakeholders as a focus
20 for developing and sharing best practices.

21 “(b) TECHNICAL ASSISTANCE TELEPHONE NUMBER
22 OR WEBSITE.—The National Coordinator shall establish
23 a toll-free telephone number or Internet website to provide
24 health care providers and patients with a single point of
25 contact to—

1 “(1) learn about Federal grants and technical
2 assistance services related to interoperable health in-
3 formation technology;

4 “(2) learn about standards, implementation
5 specifications, and certification criteria adopted
6 under section 3004(b);

7 “(3) learn about regional and local health infor-
8 mation networks for assistance with health informa-
9 tion technology; and

10 “(4) disseminate additional information deter-
11 mined by the National Coordinator.

12 “(c) AUTHORIZATION OF APPROPRIATIONS.—There
13 is authorized to be appropriated, such sums as may be
14 necessary for each of the fiscal years 2009 and 2010 to
15 carry out this section.”.

16 **SEC. 102. TRANSITIONS.**

17 (a) ONCHIT.—To the extent consistent with section
18 3001 of the Public Health Service Act, as added by section
19 101, all functions, personnel, assets, liabilities, and admin-
20 istrative actions applicable to the National Coordinator for
21 Health Information Technology appointed under Execu-
22 tive Order 13335 or the Office of such National Coordi-
23 nator on the date before the date of the enactment of this
24 Act shall be transferred to the National Coordinator ap-
25 pointed under section 3001(a) of such Act and the Office

1 of such National Coordinator as of the date of the enact-
2 ment of this Act.

3 (b) AHIC.—

4 (1) To the extent consistent with sections 3002
5 and 3003 of the Public Health Service Act, as added
6 by section 101, all functions, personnel, assets, and
7 liabilities applicable to the American Health Infor-
8 mation Community created in response to Executive
9 Order 13335 as of the day before the date of the en-
10 actment of this Act shall be transferred to the HIT
11 Policy Committee or the HIT Standards Committee,
12 established under section 3002(a) or 3003(a) of such
13 Act, as appropriate, as of the date of the enactment
14 of this Act.

15 (2) In carrying out section 3003(b)(1)(A) of the
16 Public Health Service Act, as so added, until rec-
17 ommendations are made by the HIT Policy Com-
18 mittee, recommendations of the HIT Standards
19 Committee shall be consistent with the most recent
20 recommendations made by the American Health In-
21 formation Community.

22 (c) RULES OF CONSTRUCTION.—

23 (1) ONCHIT.—Nothing in section 3001 of the
24 Public Health Service Act, as added by section 101,
25 or subsection (a) shall be construed as requiring the

1 creation of a new entity to the extent that the Office
2 of the National Coordinator for Health Information
3 Technology established pursuant to Executive Order
4 13335 is consistent with the provisions of such sec-
5 tion 3001.

6 (2) AHIC.—Nothing in sections 3002 or 3003
7 of the Public Health Service Act, as added by sec-
8 tion 101, or subsection (b) shall be construed as re-
9 quiring the creation of a new entity to the extent
10 that the American Health Information Community
11 created in response to Executive Order 13335 is
12 consistent with the provisions of such sections 3002
13 and 3003.

14 **PART 2—APPLICATION AND USE OF ADOPTED**
15 **HEALTH INFORMATION TECHNOLOGY**
16 **STANDARDS; REPORTS**

17 **SEC. 111. COORDINATION OF FEDERAL ACTIVITIES WITH**
18 **ADOPTED STANDARDS AND IMPLEMENTA-**
19 **TION SPECIFICATIONS.**

20 (a) SPENDING ON HEALTH INFORMATION TECH-
21 NOLOGY SYSTEMS.—As each agency (as defined in the Ex-
22 ecutive Order issued on August 22, 2006, relating to pro-
23 moting quality and efficient health care in Federal govern-
24 ment administered or sponsored health care programs) im-
25 plements, acquires, or upgrades health information tech-

1 nology systems used for the direct exchange of individually
2 identifiable health information between agencies and with
3 non-Federal entities, it shall utilize, where available,
4 health information technology systems and products that
5 meet standards and implementation specifications adopted
6 under section 3004(b) of the Public Health Service Act,
7 as added by section 101.

8 (b) FEDERAL INFORMATION COLLECTION ACTIVI-
9 TIES.—With respect to a standard or implementation
10 specification adopted under section 3004(b) of the Public
11 Health Service Act, as added by section 101, the President
12 shall take measures to ensure that Federal activities in-
13 volving the broad collection and submission of health in-
14 formation are consistent with such standard or specifica-
15 tion, respectively, within three years after the date of such
16 adoption.

17 (c) APPLICATION OF DEFINITIONS.—The definitions
18 contained in section 3000 of the Public Health Service
19 Act, as added by section 101, shall apply for purposes of
20 this part.

21 **SEC. 112. APPLICATION TO PRIVATE ENTITIES.**

22 Private entities that enter into a contract with the
23 Federal Government to carry out health activities of the
24 Federal Government shall adopt the standards and imple-
25 mentation specifications adopted under section 3004(b) of

1 the Public Health Service Act, as added by section 101,
2 for the purpose of such activities.

3 **SEC. 113. REPORTS.**

4 (a) IN GENERAL.—The Secretary of Health and
5 Human Services shall submit to the Committee on Health,
6 Education, Labor, and Pensions and the Committee on
7 Commerce, Science, and Transportation of the Senate and
8 the Committee on Energy and Commerce and the Com-
9 mittee on Science and Technology of the House of Rep-
10 resentatives, on an annual basis, a report that—

11 (1) describes the specific actions that have been
12 taken by the Federal Government and private enti-
13 ties to facilitate the adoption of an interoperable na-
14 tionwide system for the electronic exchange of health
15 information;

16 (2) describes barriers to the adoption of such a
17 nationwide system; and

18 (3) contains recommendations to achieve full
19 implementation of such a nationwide system.

20 (b) REIMBURSEMENT INCENTIVE STUDY.—The Sec-
21 retary of Health and Human Services shall carry out, or
22 contract with a private entity to carry out, a study that
23 examines methods to create efficient reimbursement incen-
24 tives for improving health care quality in Federally quali-
25 fied health centers, rural health clinics, and free clinics.

1 **Subtitle B—Incentives for the Use**
2 **of Health Information Technology**

3 **SEC. 121. GRANT, LOAN, AND DEMONSTRATION PROGRAMS.**

4 Title XXX of the Public Health Service Act, as added
5 by section 101, is amended by adding at the end the fol-
6 lowing new subtitle:

7 **“Subtitle B—Incentives for the Use**
8 **of Health Information Technology**

9 **“SEC. 3011. GRANTS AND LOANS TO FACILITATE THE WIDE-**
10 **SPREAD ADOPTION OF QUALIFIED HEALTH**
11 **INFORMATION TECHNOLOGY.**

12 “(a) COMPETITIVE GRANTS TO FACILITATE THE
13 WIDESPREAD ADOPTION OF HEALTH INFORMATION
14 TECHNOLOGY.—

15 “(1) IN GENERAL.—The National Coordinator
16 may award competitive grants to eligible entities to
17 purchase qualified health information technology.

18 “(2) QUALIFIED HEALTH INFORMATION TECH-
19 NOLOGY.—For purposes of this section, the term
20 ‘qualified health information technology’ means
21 health information technology that consists of hard-
22 ware, software, or the provision of support services
23 and that—

24 “(A) enables the protection of health infor-
25 mation, in accordance with applicable law;

1 “(B) is (or is necessary for the operation
2 of) an electronic health records system, includ-
3 ing the provision of decision support, and physi-
4 cian order entry for medications;

5 “(C) has the ability to allow timely and
6 permissible access to patient information and to
7 transmit and exchange health information
8 among providers, patients, or insurers; and

9 “(D) is certified under subtitle A to be in
10 compliance with any applicable standards and
11 implementation specifications adopted under
12 section 3004(b).

13 “(3) ELIGIBILITY.—To be eligible to receive a
14 grant under paragraph (1) an entity shall—

15 “(A) submit to the National Coordinator
16 an application at such time and in such manner
17 as the National Coordinator may require, and
18 containing—

19 “(i) a plan on how the entity intends
20 to maintain and support the qualified
21 health information technology that would
22 be purchased with amounts under such
23 grant, including the type of resources ex-
24 pected to be involved; and

1 “(ii) any such other information as
2 the National Coordinator may require;

3 “(B) submit to the National Coordinator a
4 strategic plan for the electronic exchange and
5 use of health information;

6 “(C) be—

7 “(i) a not for profit hospital or a Fed-
8 erally qualified health center (as defined in
9 section 1861(aa)(4) of the Social Security
10 Act);

11 “(ii) an individual or group practice;
12 or

13 “(iii) another health care provider not
14 described in clause (i) or (ii);

15 “(D) demonstrate significant financial
16 need; and

17 “(E) provide matching funds in accordance
18 with paragraph (5).

19 “(4) USE OF FUNDS.—Amounts received under
20 a grant under this subsection shall be used to facili-
21 tate the purchase of qualified health information
22 technology.

23 “(5) MATCHING REQUIREMENT.—To be eligible
24 for a grant under this subsection an entity shall con-
25 tribute non-Federal contributions to the costs of car-

1 rying out the activities for which the grant is award-
2 ed in an amount equal to \$1 for each \$3 of Federal
3 funds provided under the grant.

4 “(6) PREFERENCE IN AWARDING GRANTS.—In
5 awarding grants under this subsection the National
6 Coordinator shall give preference to—

7 “(A) a small health care provider;

8 “(B) eligible entities that are located in
9 rural, frontier, and other areas that serve unin-
10 sured, underinsured, and medically underserved
11 individuals (regardless of whether such area is
12 urban, rural, or frontier);

13 “(C) eligible entities that will link, to the
14 extent practicable, to local or regional health in-
15 formation plan or plans; and

16 “(D) an entity described in paragraph
17 (3)(C)(iii) that is a nonprofit health care pro-
18 vider.

19 “(7) ADDITIONAL SOURCES OF FUNDING FOR
20 HEALTH INFORMATION TECHNOLOGY.—Funding
21 made available under this subsection is in addition
22 to funding which may be used toward the acquisition
23 and utilization of health information technology
24 under other law, which includes the following:

1 “(A) Medicaid transformation grants
2 under section 1903(z) of the Social Security
3 Act.

4 “(B) Grants or funding available through
5 the Agency for Healthcare Research and Qual-
6 ity.

7 “(C) Grants or funding that may be avail-
8 able through the Health Resources and Services
9 Administration for investment in health infor-
10 mation technologies or telehealth.

11 “(D) Grants or funding that may be avail-
12 able through the Department of Agriculture’s
13 Rural Development Telecommunications Pro-
14 gram for investment in telemedicine.

15 “(b) COMPETITIVE GRANTS TO STATES AND INDIAN
16 TRIBES FOR THE DEVELOPMENT OF LOAN PROGRAMS TO
17 FACILITATE THE WIDESPREAD ADOPTION OF QUALIFIED
18 HEALTH INFORMATION TECHNOLOGY.—

19 “(1) IN GENERAL.—The National Coordinator
20 may award competitive grants to eligible entities for
21 the establishment of programs for loans to health
22 care providers to purchase qualified health informa-
23 tion technology.

24 “(2) ESTABLISHMENT OF FUND.—To be eligi-
25 ble to receive a competitive grant under this sub-

1 section, an eligible entity shall establish a qualified
2 health information technology loan fund (referred to
3 in this subsection as a ‘Loan Fund’) and comply
4 with the other requirements contained in this sec-
5 tion. A grant to an eligible entity under this sub-
6 section shall be deposited in the Loan Fund estab-
7 lished by the eligible entity. No funds authorized by
8 other provisions of this subtitle to be used for other
9 purposes specified in this subtitle shall be deposited
10 in any Loan Fund.

11 “(3) ELIGIBLE ENTITY DEFINED.—For pur-
12 poses of this subsection, the term ‘eligible entity’
13 means a State or Indian tribe (as defined in the In-
14 dian Self-Determination and Education Assistance
15 Act) that—

16 “(A) submits to the National Coordinator
17 an application at such time, in such manner,
18 and containing such information as the Na-
19 tional Coordinator may require;

20 “(B) submits to the National Coordinator
21 a strategic plan in accordance with paragraph
22 (4);

23 “(C) establishes a Loan Fund in accord-
24 ance with paragraph (2);

1 “(D) requires that health care providers
2 receiving such loans—

3 “(i) link, to the extent practicable, to
4 a local or regional health information net-
5 work;

6 “(ii) consult with the Health Informa-
7 tion Technology Resource Center estab-
8 lished in section 914(d) to access the
9 knowledge and experience of existing initia-
10 tives regarding the successful implementa-
11 tion and effective use of health information
12 technology; and

13 “(iii) agree to notify patients if their
14 individually identifiable health information
15 is wrongfully disclosed in accordance with
16 section 302 of the **【short title】**; and

17 “(iv) submit to the State or Indian
18 tribe, respectively, a plan on how the State
19 or Indian tribe, respectively, intends to
20 maintain and support the qualified health
21 information technology that would be pur-
22 chased with such loans, including the type
23 of resources expected to be involved and
24 any such other information as the State or

1 Indian Tribe, respectively, may require;
2 and

3 “(E) provides matching funds in accord-
4 ance with paragraph (8).

5 “(4) STRATEGIC PLAN.—

6 “(A) IN GENERAL.—An eligible entity that
7 receives a grant under this subsection shall an-
8 nually prepare a strategic plan that identifies
9 the intended uses of amounts available to the
10 Loan Fund of the eligible entity.

11 “(B) CONTENTS.—A strategic plan under
12 subparagraph (A), with respect to a Loan Fund
13 of an eligible entity, shall include—

14 “(i) a list of the projects to be as-
15 sisted through the Loan Fund in the first
16 fiscal year that begins after the date on
17 which the plan is submitted;

18 “(ii) a description of the criteria and
19 methods established for the distribution of
20 funds from the Loan Fund; and

21 “(iii) a description of the financial
22 status of the Loan Fund and the short-
23 term and long-term goals of the Loan
24 Fund.

25 “(5) USE OF FUNDS.—

1 “(A) IN GENERAL.—Amounts deposited in
2 a Loan Fund, including loan repayments and
3 interest earned on such amounts, shall be used
4 only for awarding loans or loan guarantees, or
5 as a source of reserve and security for leveraged
6 loans, the proceeds of which are deposited in
7 the Loan Fund established under paragraph
8 (1). Loans under this section may be used by
9 a health care provider to purchase qualified
10 health information technology.

11 “(B) LIMITATION.—Amounts received by
12 an eligible entity under this subsection may not
13 be used—

14 “(i) for the purchase or other acquisi-
15 tion of any health information technology
16 system that is not a qualified health infor-
17 mation technology;

18 “(ii) to conduct activities for which
19 Federal funds are expended under this
20 title; or

21 “(iii) for any purpose other than mak-
22 ing loans to health care providers in ac-
23 cordance with this section.

24 “(6) TYPES OF ASSISTANCE.—Except as other-
25 wise limited by applicable State law, amounts depos-

1 ited into a Loan Fund under this subsection may
2 only be used for the following:

3 “(A) To award loans that comply with the
4 following:

5 “(i) The interest rate for each loan
6 shall be less than or equal to the market
7 interest rate.

8 “(ii) The principal and interest pay-
9 ments on each loan shall commence not
10 later than 1 year after the loan was award-
11 ed, and each loan shall be fully amortized
12 not later than 10 years after the date of
13 the loan.

14 “(iii) The Loan Fund shall be cred-
15 ited with all payments of principal and in-
16 terest on each loan awarded from the Loan
17 Fund.

18 “(B) To guarantee, or purchase insurance
19 for, a local obligation (all of the proceeds of
20 which finance a project eligible for assistance
21 under this subsection) if the guarantee or pur-
22 chase would improve credit market access or re-
23 duce the interest rate applicable to the obliga-
24 tion involved.

1 “(C) As a source of revenue or security for
2 the payment of principal and interest on rev-
3 enue or general obligation bonds issued by the
4 eligible entity if the proceeds of the sale of the
5 bonds will be deposited into the Loan Fund.

6 “(D) To earn interest on the amounts de-
7 posited into the Loan Fund.

8 “(7) ADMINISTRATION OF LOAN FUNDS.—

9 “(A) COMBINED FINANCIAL ADMINISTRA-
10 TION.—An eligible entity may (as a convenience
11 and to avoid unnecessary administrative costs)
12 combine, in accordance with applicable State
13 law, the financial administration of a Loan
14 Fund established under this subsection with the
15 financial administration of any other revolving
16 fund established by the entity if otherwise not
17 prohibited by the law under which the Loan
18 Fund was established.

19 “(B) COST OF ADMINISTERING FUND.—
20 Each eligible entity may annually use not to ex-
21 ceed 4 percent of the funds provided to the en-
22 tity under a grant under this subsection to pay
23 the reasonable costs of the administration of
24 the programs under this section, including the
25 recovery of reasonable costs expended to estab-

1 lish a Loan Fund which are incurred after the
2 date of the enactment of this title.

3 “(C) GUIDANCE AND REGULATIONS.—The
4 National Coordinator shall publish guidance
5 and promulgate regulations as may be nec-
6 essary to carry out the provisions of this sub-
7 section, including—

8 “(i) provisions to ensure that each eli-
9 gible entity commits and expends funds al-
10 lotted to the entity under this subsection
11 as efficiently as possible in accordance with
12 this title and applicable State laws; and

13 “(ii) guidance to prevent waste, fraud,
14 and abuse.

15 “(D) PRIVATE SECTOR CONTRIBUTIONS.—

16 “(i) IN GENERAL.—A Loan Fund es-
17 tablished under this subsection may accept
18 contributions from private sector entities,
19 except that such entities may not specify
20 the recipient or recipients of any loan
21 issued under this subsection.

22 “(ii) AVAILABILITY OF INFORMA-
23 TION.—An eligible entity shall make pub-
24 licly available the identity of, and amount
25 contributed by, any private sector entity

1 under clause (i) and may issue letters of
2 commendation or make other awards (that
3 have no financial value) to any such entity.

4 “(8) MATCHING REQUIREMENTS.—

5 “(A) IN GENERAL.—The National Coordi-
6 nator may not make a grant under paragraph
7 (1) to an eligible entity unless the entity agrees
8 to make available (directly or through donations
9 from public or private entities) non-Federal
10 contributions in cash toward the costs of the
11 program to be implemented under the grant in
12 an amount equal to not less than \$1 for each
13 \$1 of Federal funds provided under the grant.

14 “(B) DETERMINATION OF AMOUNT OF
15 NON-FEDERAL CONTRIBUTION.—In determining
16 the amount of non-Federal contributions that
17 an eligible entity has provided pursuant to sub-
18 paragraph (A), the National Coordinator may
19 not include any amounts provided to the entity
20 by the Federal Government.

21 “(9) REPORTS.—The National Coordinator
22 shall annually submit to the Committee on Health,
23 Education, Labor, and Pensions and the Committee
24 on Finance of the Senate, and the Committee on
25 Energy and Commerce of the House of Representa-

1 tives, a report summarizing the reports received by
2 the National Coordinator from each eligible entity
3 that receives a grant under this subsection.

4 “(c) COMPETITIVE GRANTS FOR THE IMPLEMENTA-
5 TION OF REGIONAL OR LOCAL HEALTH INFORMATION
6 TECHNOLOGY PLANS.—

7 “(1) IN GENERAL.—The National Coordinator
8 may award competitive grants to eligible entities to
9 implement regional or local health information plans
10 to improve health care quality and efficiency through
11 the electronic exchange and use of health informa-
12 tion.

13 “(2) ELIGIBILITY.—To be eligible to receive a
14 grant under paragraph (1) an entity shall—

15 “(A) facilitate the electronic exchange and
16 use of health information within the local or re-
17 gional area and among local and regional areas;

18 “(B) demonstrate financial need to the Na-
19 tional Coordinator;

20 “(C) demonstrate that one of its principal
21 missions or purposes is to use information tech-
22 nology to improve health care quality and effi-
23 ciency;

24 “(D) adopt bylaws, memoranda of under-
25 standing, or other charter documents that dem-

1 onstrate that the governance structure and de-
2 cisionmaking processes of such entity allow for
3 participation on an ongoing basis by multiple
4 stakeholders within a community, including—

5 “(i) physicians (as defined in section
6 1861(r) of the Social Security Act), includ-
7 ing physicians that provide services to low
8 income populations and populations that
9 are uninsured, underinsured, and medically
10 underserved (including such populations in
11 urban and rural areas);

12 “(ii) hospitals (including hospitals
13 that provide services to low income and un-
14 derserved populations);

15 “(iii) pharmacists or pharmacies;

16 “(iv) health insurance plans;

17 “(v) health centers (as defined in sec-
18 tion 330(b)) and Federally qualified health
19 centers (as defined in section 1861(aa)(4)
20 of the Social Security Act);

21 “(vi) rural health clinics (as defined in
22 section 1861(aa) of the Social Security
23 Act);

24 “(vii) patient or consumer organiza-
25 tions;

- 1 “(viii) employers;
- 2 “(ix) public health agencies; and
- 3 “(x) any other health care providers
- 4 or other entities, as determined appro-
- 5 priate by the National Coordinator;
- 6 “(E) demonstrate the participation, to the
- 7 extent practicable, of stakeholders in the elec-
- 8 tronic exchange and use of health information
- 9 within the local or regional health information
- 10 plan pursuant to subparagraph (D);
- 11 “(F) adopt nondiscrimination and conflict
- 12 of interest policies that demonstrate a commit-
- 13 ment to open, fair, and nondiscriminatory par-
- 14 ticipation in the regional or local health infor-
- 15 mation plan by all stakeholders;
- 16 “(G) comply with applicable standards and
- 17 implementation specifications adopted under
- 18 this title;
- 19 “(H) prepare and submit to the National
- 20 Coordinator an application in accordance with
- 21 paragraph (3); and
- 22 “(I) agree to provide matching funds in ac-
- 23 cordance with paragraph (5).
- 24 “(3) APPLICATION.—

1 “(A) IN GENERAL.—To be eligible to re-
2 ceive a grant under paragraph (1), an entity
3 shall submit to the National Coordinator an ap-
4 plication at such time, in such manner, and
5 containing such information (in addition to in-
6 formation required under subparagraph (B), as
7 the National Coordinator may require.

8 “(B) REQUIRED INFORMATION.—At a
9 minimum, an application submitted under this
10 paragraph shall include—

11 “(i) clearly identified short-term and
12 long-term objectives of the regional or local
13 health information plan;

14 “(ii) a descriptive and reasoned esti-
15 mate of costs of the hardware, software,
16 training, and other services necessary to
17 implement the regional or local health in-
18 formation plan;

19 “(iii) a strategy that includes initia-
20 tives to improve health care quality and ef-
21 ficiency;

22 “(iv) a plan that describes provisions
23 to encourage the electronic exchange and
24 use of health information by all physicians,
25 including single physician practices and

1 small physician groups participating in the
2 health information plan;

3 “(v) a plan to ensure the privacy and
4 security of individually identifiable health
5 information that is consistent with applica-
6 ble Federal and State law;

7 “(vi) a governance plan that defines
8 the manner in which the stakeholders shall
9 jointly make policy and operational deci-
10 sions on an ongoing basis;

11 “(vii) a financial or business plan that
12 describes—

13 “(I) the sustainability of the
14 plan;

15 “(II) the financial costs and ben-
16 efits of the plan; and

17 “(III) the entities to which such
18 costs and benefits will accrue;

19 “(viii) a plan on how the entity in-
20 volved intends to maintain and support the
21 regional or local health information plan,
22 including the type of resources expected to
23 be involved; and

24 “(ix) in the case of an applicant entity
25 that is unable to demonstrate the partici-

1 pation of all stakeholders pursuant to
2 paragraph (2)(C), the justification from
3 the entity for any such nonparticipation.

4 “(4) USE OF FUNDS.—Amounts received under
5 a grant under paragraph (1) shall be used to estab-
6 lish and implement a regional or local health infor-
7 mation plan in accordance with this subsection.

8 “(5) PREFERENCE.—In awarding grants under
9 paragraph (1), the Secretary shall give preference to
10 eligible entities that intend to use amounts received
11 under a grant to establish or implement a regional
12 or local health information plan that encompasses
13 communities with health disparities or areas that
14 serve uninsured, underinsured, and medically under-
15 served individuals (including urban and rural areas).

16 “(6) MATCHING REQUIREMENT.—

17 “(A) IN GENERAL.—The National Coordi-
18 nator may not make a grant under this sub-
19 section to an entity unless the entity agrees
20 that, with respect to the costs to be incurred by
21 the entity in carrying out the infrastructure
22 program for which the grant was awarded, the
23 entity will make available (directly or through
24 donations from public or private entities) non-
25 Federal contributions toward such costs in an

1 amount equal to not less than 50 percent of
2 such costs (\$1 for each \$2 of Federal funds
3 provided under the grant).

4 “(B) DETERMINATION OF AMOUNT CON-
5 TRIBUTED.—Non-Federal contributions re-
6 quired under subparagraph (A) may be in cash
7 or in kind, fairly evaluated, including equip-
8 ment, technology, or services. Amounts provided
9 by the Federal Government, or services assisted
10 or subsidized to any significant extent by the
11 Federal Government, may not be included in
12 determining the amount of such non-Federal
13 contributions.

14 “(d) REPORTS.—Not later than 1 year after the date
15 on which the first grant is awarded under this section,
16 and annually thereafter during the grant period, an entity
17 that receives a grant under this section shall submit to
18 the National Coordinator a report on the activities carried
19 out under the grant involved. Each such report shall in-
20 clude—

21 “(1) a description of the financial costs and
22 benefits of the project involved and of the entities to
23 which such costs and benefits accrue;

24 “(2) an analysis of the impact of the project on
25 health care quality and safety;

1 “(3) a description of any reduction in duplica-
2 tive or unnecessary care as a result of the project in-
3 volved;

4 “(4) a description of the efforts of recipients
5 under this section to facilitate secure patient access
6 to health information; and

7 “(5) other information as required by the Na-
8 tional Coordinator.

9 “(e) REQUIREMENT TO IMPROVE QUALITY OF CARE
10 AND DECREASE IN COSTS.—The National Coordinator
11 shall annually evaluate the activities conducted under this
12 section and shall, in awarding grants, implement the les-
13 sons learned from such evaluation in a manner so that
14 awards made subsequent to each such evaluation are made
15 in a manner that, in the determination of the National
16 Coordinator, will result in the greatest improvement in
17 quality of care and decrease in costs.

18 “(f) LIMITATION.—An eligible entity may only receive
19 one non-renewable grant under subsection (a), one non-
20 renewable grant under subsection (b), and one non-renew-
21 able grant under subsection (c).

22 “(g) SMALL HEALTH CARE PROVIDER.—For pur-
23 poses of this section, the term ‘small health care provider’
24 means a health care provider that has an average of 10

1 or fewer full-time equivalent employees during the period
2 involved.

3 “(h) AUTHORIZATION OF APPROPRIATIONS.—

4 “(1) IN GENERAL.—For the purpose of car-
5 rying out subsections (a) through (d), there is au-
6 thorized to be appropriated such sums as may be
7 necessary for each of the fiscal years 2009 through
8 2013.

9 “(2) AVAILABILITY.—Amounts appropriated
10 under paragraph (1) shall remain available through
11 fiscal year 2013.

12 **“SEC. 3012. DEMONSTRATION PROGRAM TO INTEGRATE IN-**
13 **FORMATION TECHNOLOGY INTO CLINICAL**
14 **EDUCATION.**

15 “(a) IN GENERAL.—The Secretary may award grants
16 under this section to carry out demonstration projects to
17 develop academic curricula integrating qualified health in-
18 formation technology in the clinical education of health
19 professionals. Such awards shall be made on a competitive
20 basis and pursuant to peer review.

21 “(b) ELIGIBILITY.—To be eligible to receive a grant
22 under subsection (a), an entity shall—

23 “(1) submit to the Secretary an application at
24 such time, in such manner, and containing such in-
25 formation as the Secretary may require;

1 “(2) submit to the Secretary a strategic plan
2 for integrating qualified health information tech-
3 nology in the clinical education of health profes-
4 sionals to reduce medical errors and enhance health
5 care quality;

6 “(3) be—

7 “(A) a health professions school;

8 “(B) a school of nursing; or

9 “(C) an institution with a graduate med-
10 ical education program;

11 “(4) provide for the collection of data regarding
12 the effectiveness of the demonstration project to be
13 funded under the grant in improving the safety of
14 patients, the efficiency of health care delivery, and
15 in increasing the likelihood that graduates of the
16 grantee will adopt and incorporate qualified health
17 information technology, in the delivery of health care
18 services; and

19 “(5) provide matching funds in accordance with
20 subsection (c).

21 “(c) USE OF FUNDS.—

22 “(1) IN GENERAL.—With respect to a grant
23 under subsection (a), an eligible entity shall—

24 “(A) use grant funds in collaboration with
25 2 or more disciplines; and

1 “(B) use grant funds to integrate qualified
2 health information technology into community-
3 based clinical education.

4 “(2) LIMITATION.—An eligible entity shall not
5 use amounts received under a grant under sub-
6 section (a) to purchase hardware, software, or serv-
7 ices.

8 “(d) MATCHING FUNDS.—

9 “(1) IN GENERAL.—The Secretary may award
10 a grant to an entity under this section only if the
11 entity agrees to make available non-Federal con-
12 tributions toward the costs of the program to be
13 funded under the grant in an amount that is not
14 less than \$1 for each \$2 of Federal funds provided
15 under the grant.

16 “(2) DETERMINATION OF AMOUNT CONTRIB-
17 UTED.—Non-Federal contributions under paragraph
18 (1) may be in cash or in kind, fairly evaluated, in-
19 cluding equipment or services. Amounts provided by
20 the Federal Government, or services assisted or sub-
21 sidized to any significant extent by the Federal Gov-
22 ernment, may not be included in determining the
23 amount of such contributions.

24 “(e) EVALUATION.—The Secretary shall take such
25 action as may be necessary to evaluate the projects funded

1 under this section and publish, make available, and dis-
2 seminate the results of such evaluations on as wide a basis
3 as is practicable.

4 “(f) REPORTS.—Not later than 1 year after the date
5 of enactment of this title, and annually thereafter, the Sec-
6 retary shall submit to the Committee on Health, Edu-
7 cation, Labor, and Pensions and the Committee on Fi-
8 nance of the Senate, and the Committee on Energy and
9 Commerce of the House of Representatives a report
10 that—

11 “(1) describes the specific projects established
12 under this section; and

13 “(2) contains recommendations for Congress
14 based on the evaluation conducted under subsection
15 (e).

16 “(g) AUTHORIZATION OF APPROPRIATIONS.—There
17 is authorized to be appropriated to carry out this section,
18 such sums as may be necessary for each of fiscal years
19 2009 through 2011.

20 “(h) SUNSET.—This section shall not apply after
21 September 30, 2011.”.

1 **TITLE II—TESTING OF HEALTH**
2 **INFORMATION TECHNOLOGY**

3 **SEC. 201. NATIONAL INSTITUTE FOR STANDARDS AND**
4 **TECHNOLOGY TESTING.**

5 (a) PILOT TESTING OF STANDARDS AND IMPLEMEN-
6 TATION SPECIFICATIONS.—In coordination with the HIT
7 Standards Committee established under section 3003 of
8 the Public Health Service Act, as added by section 101,
9 with respect to the development of standards and imple-
10 mentation specifications under such section, the Director
11 of the National Institute for Standards and Technology
12 shall test such standards and specifications in order to as-
13 sure the efficient implementation and use of such stand-
14 ards and specifications.

15 (b) VOLUNTARY TESTING PROGRAM.—In coordina-
16 tion with the HIT Standards Committee established under
17 section 3003 of the Public Health Service Act, as added
18 by section 101, with respect to the development of stand-
19 ards and implementation specifications under such sec-
20 tion, the Director of the National Institute of Standards
21 and Technology shall support the establishment of a con-
22 formance testing infrastructure, including the develop-
23 ment of technical test beds. The development of this con-
24 formance testing infrastructure may include a program to

1 accredit independent, non-federal laboratories to perform
2 testing.

3 **SEC. 202. RESEARCH AND DEVELOPMENT PROGRAMS.**

4 (a) HEALTH CARE INFORMATION ENTERPRISE INTE-
5 GRATION RESEARCH CENTERS.—

6 (1) IN GENERAL.—The Director of the National
7 Institute of Standards and Technology, in consulta-
8 tion the Director of the National Science Foundation
9 and other appropriate Federal agencies, shall estab-
10 lish a program of assistance to institutions of higher
11 education (or consortia thereof which may include
12 nonprofit entities and Federal Government labora-
13 tories) to establish multidisciplinary Centers for
14 Health Care Information Enterprise Integration.

15 (2) REVIEW; COMPETITION.—Grants shall be
16 awarded under this subsection on a merit-reviewed,
17 competitive basis.

18 (3) PURPOSE.—The purposes of the Centers de-
19 scribed in paragraph (1) shall be—

20 (A) to generate innovative approaches to
21 health care information enterprise integration
22 by conducting cutting-edge, multidisciplinary
23 research on the systems challenges to health
24 care delivery; and

1 (B) the development and use of health in-
2 formation technologies and other complemen-
3 tary fields.

4 (4) RESEARCH AREAS.—Research areas may in-
5 clude—

6 (A) interfaces between human information
7 and communications technology systems;

8 (B) voice-recognition systems;

9 (C) software that improves interoperability
10 and connectivity among health information sys-
11 tems;

12 (D) software dependability in systems crit-
13 ical to health care delivery;

14 (E) measurement of the impact of informa-
15 tion technologies on the quality and productivity
16 of health care;

17 (F) health information enterprise manage-
18 ment; and

19 (G) health information technology security
20 and integrity.

21 (5) APPLICATIONS.—An institution of higher
22 education (or a consortium thereof) seeking funding
23 under this subsection shall submit an application to
24 the Director of the National Institute of Standards
25 and Technology at such time, in such manner, and

1 containing such information as the Director may re-
2 quire. The application shall include, at a minimum,
3 a description of—

4 (A) the research projects that will be un-
5 dertaken by the Center established pursuant to
6 assistance under paragraph (1) and the respec-
7 tive contributions of the participating entities;

8 (B) how the Center will promote active col-
9 laboration among scientists and engineers from
10 different disciplines, such as information tech-
11 nology, biologic sciences, management, social
12 sciences, and other appropriate disciplines;

13 (C) technology transfer activities to dem-
14 onstrate and diffuse the research results, tech-
15 nologies, and knowledge; and

16 (D) how the Center will contribute to the
17 education and training of researchers and other
18 professionals in fields relevant to health infor-
19 mation enterprise integration.

20 (b) NATIONAL INFORMATION TECHNOLOGY RE-
21 SEARCH AND DEVELOPMENT PROGRAM.—The National
22 High-Performance Computing Program established by
23 section 101 of the High-Performance Computing Act of
24 1991 (15 U.S.C. 5511) shall coordinate Federal research
25 and development programs related to the development and

1 deployment of health information technology, including ac-
2 tivities related to—

3 (1) computer infrastructure;

4 (2) data security;

5 (3) development of large-scale, distributed, reli-
6 able computing systems;

7 (4) wired, wireless, and hybrid high-speed net-
8 working;

9 (5) development of software and software-inten-
10 sive systems;

11 (6) human-computer interaction and informa-
12 tion management technologies; and

13 (7) the social and economic implications of in-
14 formation technology.

15 **TITLE III—PRIVACY AND** 16 **SECURITY PROVISIONS**

17 **SEC. 300. DEFINITIONS.**

18 In this title, except as specified otherwise:

19 (1) **BREACH.**—The term “breach” means the
20 unauthorized acquisition, disclosure, or loss of pro-
21 tected health information which compromises the se-
22 curity, privacy, or integrity of protected health infor-
23 mation maintained by or on behalf of a person.

24 (2) **BUSINESS ASSOCIATE.**—The term “business
25 associate” has the meaning given such term in sec-

1 tion 160.103 of title 45, Code of Federal Regula-
2 tions.

3 (3) COVERED ENTITY.—The term “covered en-
4 tity” has the meaning given such term in section
5 160.103 of title 45, Code of Federal Regulations.

6 (4) DISCLOSE.—The terms “disclose” and “dis-
7 closure” have the meaning given the term “disclo-
8 sure” in section 160.103 of title 45, Code of Federal
9 Regulations.

10 (5) ENCRYPTION.—The term “encryption” has
11 the meaning given such term in section 164.304 of
12 title 45, Code of Federal Regulations.

13 (6) HEALTH CARE OPERATIONS.—The term
14 “health care operation” has the meaning given such
15 term in section 164.501 of title 45, Code of Federal
16 Regulations.

17 (7) HEALTH CARE PROVIDER.—The term
18 “health care provider” has the meaning given such
19 term in section 160.103 of title 45, Code of Federal
20 Regulations.

21 (8) PERSONAL HEALTH RECORD.—The term
22 “personal health record” means an electronic, cumu-
23 lative record of health-related information on an in-
24 dividual that is drawn from multiple sources and

1 that is created, gathered, and managed by the indi-
2 vidual.

3 (9) PROTECTED HEALTH INFORMATION.—The
4 term “protected health information” has the mean-
5 ing given such term under section 160.103 of title
6 45, Code of Federal Regulations.

7 (10) SECRETARY.—The term “Secretary”
8 means the Secretary of Health and Human Services.

9 (11) SECURITY.—The term “security” has the
10 meaning given such term in section 164.304 of title
11 45, Code of Federal Regulations.

12 (12) STATE.—The term “State” means each of
13 the several States, the District of Columbia, Puerto
14 Rico, the Virgin Islands, Guam, American Samoa,
15 and the Northern Mariana Islands.

16 (13) USE.—The term “use” has the meaning
17 given such term in section 160.103 of title 45, Code
18 of Federal Regulations.

19 (14) VENDOR OF PERSONAL HEALTH
20 RECORDS.—The term “vendor” means an entity that
21 offers or maintains a personal health record.

1 **Subtitle A—Security Provisions**

2 **SEC. 301. APPLICATION OF SECURITY PROVISIONS AND** 3 **PENALTIES TO BUSINESS ASSOCIATES OF** 4 **COVERED ENTITIES; ANNUAL GUIDANCE ON** 5 **SECURITY PROVISIONS.**

6 (a) APPLICATION OF SECURITY PROVISIONS.—Sec-
7 tions 164.308, 164.310, and 164.312 of title 45, Code of
8 Federal Regulations, shall apply to a business associate
9 of a covered entity in the same manner that such sections
10 apply to the covered entity.

11 (b) APPLICATION OF CIVIL AND CRIMINAL PEN-
12 ALTIES.—Sections 1176 and 1177 of the Social Security
13 Act shall apply to a business associate of a covered entity
14 with respect to a section applied under subsection (a) to
15 such business associate in the same manner that such sec-
16 tions apply to a covered entity with respect to such section.

17 (c) ANNUAL GUIDANCE.—For the first year begin-
18 ning after the date of the enactment of this Act and annu-
19 ally thereafter, the Secretary of Health and Human Serv-
20 ices shall annually issue guidance on the latest safeguard
21 technologies for use in carrying out the sections described
22 in subsection (a).

23 **SEC. 302. NOTIFICATION IN THE CASE OF BREACH.**

24 (a) IN GENERAL.—A covered entity that accesses,
25 maintains, retains, modifies, records, stores, destroys, or

1 otherwise holds, uses, or discloses protected health infor-
2 mation shall, in the case of a breach of such information
3 that is discovered by the covered entity, notify each indi-
4 vidual whose protected health information has been, or is
5 reasonably believed by the covered entity to have been,
6 accessed or acquired as a result of such breach if the un-
7 authorized use of such information could reasonably result
8 in substantial harm, embarrassment, inconvenience, or un-
9 fairness to the individual.

10 (b) NOTIFICATION OF COVERED ENTITY BY BUSI-
11 NESS ASSOCIATE.—A business associate of a covered enti-
12 ty that accesses, maintains, retains, modifies, records,
13 stores, destroys, or otherwise holds, uses, or discloses pro-
14 tected health information shall, following the discovery of
15 a breach of such information, notify the covered entity of
16 such breach. Such notice shall include the identification
17 of each individual whose protected health information has
18 been, or is reasonably believed to have been, accessed or
19 acquired during such breach.

20 (c) BREACHES TREATED AS DISCOVERED.—For pur-
21 poses of this section, a breach shall be treated as discov-
22 ered by a covered entity or by a business associate as of
23 the first day on which such breach is known to such entity
24 or associate, respectively, (including any person that is an
25 employee, officer, or other agent of such entity or asso-

1 ciate, respectively) or should reasonably have been known
2 to such entity or associate (or person) to have occurred.

3 (d) TIMELINESS OF NOTIFICATION.—

4 (1) IN GENERAL.—All notifications required
5 under this section shall be made not later than 15
6 business days, or earlier if the Secretary determines
7 appropriate, after the discovery of a breach by the
8 covered entity involved (or business associate in-
9 volved in the case of a notification required under
10 subsection (b)).

11 (2) BURDEN OF PROOF.—The covered entity in-
12 volved (or business associate involved in the case of
13 a notification required under subsection (b)), shall
14 have the burden of demonstrating that all notifica-
15 tions were made as required under this subtitle, in-
16 cluding evidence demonstrating the necessity of any
17 delay.

18 (e) METHODS OF NOTICE.—

19 (1) INDIVIDUAL NOTICE.—Notice required
20 under this section to be provided to an individual,
21 with respect to a breach, shall be provided promptly
22 and in the following form:

23 (A) Written notification by first-class mail
24 to the individual (or the next of kin of the indi-
25 vidual if the individual is deceased) at the last

1 known address of the individual or the next of
2 kin, respectively. The notification may be sent
3 in one or more mailings as information is avail-
4 able.

5 (B) In the case where there is insufficient,
6 or out-of-date contact information that pre-
7 cludes direct written notification to the indi-
8 vidual, a substitute form of notice shall be pro-
9 vided, including a conspicuous posting on the
10 home page of the Web site of the covered entity
11 involved and notice in major print and broad-
12 cast media, including major media in geo-
13 graphic areas where the individuals affected by
14 the breach likely reside. Such a notice in media
15 will include a toll-free phone number where an
16 individual can learn whether or not the individ-
17 ual's protected health information is possibly in-
18 cluded in the breach.

19 (C) In any case deemed by the covered en-
20 tity involved to require urgency because of pos-
21 sible imminent misuse of protected health infor-
22 mation, the covered entity, in addition to notice
23 provided under subparagraph (A), may provide
24 information to individuals by telephone or other
25 means, as appropriate.

1 (2) MEDIA NOTICE.—Notice shall be provided
2 to prominent media outlets serving a State or juris-
3 diction, following the discovery of a breach described
4 in subsection (a), if the protected health information
5 of more than 500 residents of such State or jurisdic-
6 tion is, or is reasonably believed to have been,
7 accessed or acquired during such breach.

8 (3) NOTICE TO SECRETARY.—Notice shall be
9 provided to the Secretary by covered entities or busi-
10 ness associates of protected health information that
11 has been lost, stolen, disclosed, or used in a breach.

12 (f) CONTENT OF NOTIFICATION.—Regardless of the
13 method by which notice is provided to individuals under
14 this section, notice of a breach shall include, to the extent
15 possible, the following:

16 (1) A brief description of what happened, in-
17 cluding the date of the breach and the date of the
18 discovery of the breach, if known.

19 (2) A description of the types of protected
20 health information that were involved in the breach
21 (such as full name, Social Security number, date of
22 birth, home address, account number, or disability
23 code).

24 (3) A statement whether the information in-
25 volved in the breach used encryption or was pro-

1 tected by another manner of safeguard, if it is deter-
2 mined that the disclosure of the manner of the safe-
3 guard would be beneficial and would not compromise
4 the security of the health information technology in-
5 volved.

6 (4) The steps individuals should take to protect
7 themselves from potential harm resulting from the
8 breach.

9 (5) A brief description of what the covered enti-
10 ty involved is doing to investigate the breach, to
11 mitigate losses, and to protect against any further
12 breaches.

13 (6) Contact procedures for individuals to ask
14 questions or learn additional information, which
15 shall include a toll-free telephone number, an e-mail
16 address, Web site, or postal address.

17 (g) DELAY OF NOTIFICATION AUTHORIZED FOR LAW
18 ENFORCEMENT PURPOSES.—If a law enforcement official
19 determines that the notification required under this sec-
20 tion would impede a criminal investigation or cause dam-
21 age to national security, such notification shall be delayed
22 in the same manner as provided under section
23 164.528(a)(2) of title 45, Code of Federal Regulations,
24 in the case of a disclosure covered under such section.

1 **SEC. 303. EDUCATION ON HEALTH INFORMATION PRIVACY**
2 **AND REPORT ON COMPLIANCE.**

3 (a) REGIONAL OFFICE PRIVACY ADVISORS.—Not
4 later than 6 months after the date of the enactment of
5 this Act, the Secretary shall designate an individual in
6 each regional office of the Department of Health and
7 Human Services to offer guidance and education to cov-
8 ered entities, business associates, and the public on their
9 rights and responsibilities related to Federal privacy re-
10 quirements for protected health information.

11 (b) REPORT ON COMPLIANCE.—

12 (1) IN GENERAL.—For the first year beginning
13 after the date of the enactment of this Act and an-
14 nually thereafter, the Secretary of Health and
15 Human Services shall prepare and submit to Con-
16 gress a report concerning complaints of alleged vio-
17 lations of the provisions of sections 301 and 302, the
18 provisions of subtitle B, and the provisions of sub-
19 parts C and E of title 45, Code of Federal Regula-
20 tions that are received by the Secretary during the
21 year for which the report is being prepared. Each
22 such report shall include, with respect to such com-
23 plaints received during the year—

24 (A) the number of such complaints;

25 (B) the resolution or disposition of each
26 such request;

1 (C) the amount of civil money penalties
2 imposed with respect to each such request, as
3 applicable;

4 (D) the number of compliance reviews con-
5 ducted and the outcome of each such review;

6 (E) the number of subpoenas or inquiries
7 issued; and

8 (F) the Secretary's plan for improving
9 compliance with and enforcement of such provi-
10 sions for the following year.

11 (2) AVAILABILITY TO PUBLIC.—Each report
12 under paragraph (1) shall be made available to the
13 public on the Internet website of the Department of
14 Health and Human Services.

15 (c) EDUCATION INITIATIVE ON USES OF HEALTH IN-
16 FORMATION.—

17 (1) IN GENERAL.—The Office for Civil Rights
18 within the Department of Health and Human Serv-
19 ices shall develop and maintain a multi-faceted na-
20 tional education initiative to enhance public trans-
21 parency regarding the uses of health information, in-
22 cluding programs to educate individuals about the
23 potential uses of their health information and effects
24 of such uses. Such programs shall be conducted in

1 a variety of languages and present information in a
2 clear and understandable manner.

3 (2) AUTHORIZATION OF APPROPRIATIONS.—

4 There is authorized to be appropriated to carry out
5 paragraph (1), \$10,000,000 for the period of fiscal
6 years 2009 through 2013.

7 **Subtitle B—Improved Privacy**
8 **Provisions**

9 **SEC. 311. APPLICATION OF PENALTIES TO BUSINESS ASSO-**
10 **CIATES OF COVERED ENTITIES FOR VIOLA-**
11 **TIONS OF PRIVACY CONTRACT REQUIRE-**
12 **MENTS.**

13 (a) APPLICATION OF CONTRACT REQUIREMENTS.—

14 In the case of a business associate of a covered entity that
15 obtains or creates protected health information pursuant
16 to a written contract (or other written arrangement) de-
17 scribed in section 164.502(e)(2) of title 45, Code of Fed-
18 eral Regulations, with such covered entity, the business
19 associate may use and disclose such protected health infor-
20 mation only if such use or disclosure, respectively, is in
21 compliance with the terms of such contract (or other ar-
22 rangement), including each applicable requirement of sec-
23 tion 164.504(e) of such title.

24 (b) APPLICATION OF KNOWLEDGE ELEMENTS ASSO-
25 CIATED WITH CONTRACTS.—Section 164.504(e)(1)(ii) of

1 title 45, Code of Federal Regulations, shall apply to a
2 business associate described in subsection (a), with respect
3 to compliance with such subsection, in the same manner
4 that such section applies to a covered entity, with respect
5 to compliance with the standards in sections 164.502(e)
6 and 164.504(e) of such title, except that in applying such
7 section 164.504(e)(1)(ii) each reference to the business as-
8 sociate, with respect to a contract, shall be treated as a
9 reference to the covered entity involved in such contract.

10 (c) APPLICATION OF CIVIL AND CRIMINAL PEN-
11 ALTIES.—If a business associate violates any provision of
12 subsection (a) or (b), the provisions of sections 1176 and
13 1177 of the Social Security Act shall apply to the business
14 associate in the same manner that such provisions apply
15 to a person who violates a provision of part C of title XI
16 of such Act.

17 **SEC. 312 REQUESTED RESTRICTIONS ON CERTAIN DISCLO-**
18 **SURES OF HEALTH INFORMATION; ACCOUNT-**
19 **ING OF CERTAIN PROTECTED HEALTH IN-**
20 **FORMATION DISCLOSURES.**

21 (a) REQUESTED RESTRICTIONS ON CERTAIN DIS-
22 CLOSURES OF HEALTH INFORMATION.—In the case that
23 an individual requests under paragraph (a)(1)(i)(A) of
24 section 164.522 of title 45, Code of Federal Regulations,
25 that a covered entity restrict the disclosure of the pro-

1 tected health information of the individual, notwith-
2 standing paragraph (a)(1)(ii) of such section, the covered
3 entity must comply with the requested restriction if—

4 (1) the disclosure is to a health plan for pur-
5 poses of carrying out payment (and is not for pur-
6 poses of carrying out treatment or health care oper-
7 ations); and

8 (2) the protected health information pertains
9 solely to a health care item or service for which the
10 health care provider involved has been paid out of
11 pocket.

12 (b) DISCLOSURES REQUIRED TO BE LIMITED TO
13 THE LIMITED DATA SET OR THE MINIMUM NEC-
14 ESSARY.—

15 (1) IN GENERAL.—A covered entity shall be in
16 compliance with section 164.502(b)(1) of title 45,
17 Code of Federal Regulations, with respect to the
18 use, disclosure, or request of protected health infor-
19 mation described in such section, only if the covered
20 entity makes reasonable efforts to limit such pro-
21 tected health information to the limited data set (as
22 defined in section 164.514(e)(2) of such title) or, if
23 needed, to the minimum necessary to accomplish the
24 intended purpose of such use, disclosure, or request,
25 respectively.

1 (2) APPLICATION OF EXCEPTIONS.—The excep-
2 tions described in section 164.502(b)(2) of title 45,
3 Code of Federal Regulations, shall apply to the re-
4 quirement under paragraph (1) as of the effective
5 date described in section 322 in the same manner
6 that such exceptions apply to section 164.502(b)(1)
7 before such date.

8 (c) ACCOUNTING OF CERTAIN PROTECTED HEALTH
9 INFORMATION DISCLOSURES REQUIRED IF COVERED EN-
10 TITY USES ELECTRONIC MEDICAL RECORD.—

11 (1) IN GENERAL.—In the case that a covered
12 entity uses or maintains an electronic medical record
13 with respect to protected health information, the ex-
14 ception under section 164.528(a)(1)(i) of title 45,
15 Code of Federal Regulations, shall not apply to dis-
16 closures made by such entity of such information.

17 (2) ELECTRONIC MEDICAL RECORD DEFINED.—
18 For purposes of paragraph (1), the term “electronic
19 medical record” means an electronic record of
20 health-related information on an individual that is
21 created, gathered, managed, and consulted by li-
22 censed clinicians and staff who are from a single or-
23 ganization and who are involved in the health care of
24 the individual.

1 **SEC. 313. CONDITIONS ON CERTAIN CONTACTS AS PART OF**
2 **HEALTH CARE OPERATIONS.**

3 (a) IN GENERAL.—A communication by a covered en-
4 tity or business associate that is about a health care item
5 or service and that encourages recipients of the commu-
6 nication to purchase or use the product or service shall
7 not be considered a health care operation for purposes of
8 subpart E of part 164 of title 45, Code of Federal Regula-
9 tions, unless the communication is made as described in
10 subparagraph (i), (ii), or (iii) of paragraph (1) of the defi-
11 nition of marketing in section 164.501 of such title.

12 (b) EFFECTIVE DATE.—Subsection (a) shall apply to
13 contracting occurring on or after the effective date speci-
14 fied under section 322.

15 **SEC. 314. STUDY ON APPLICATION OF PRIVACY AND SECU-**
16 **RITY REQUIREMENTS TO VENDORS OF PER-**
17 **SONAL HEALTH RECORDS.**

18 Not later than one year after the date of the enact-
19 ment of this Act, the Secretary of Health and Human
20 Services, in consultation with the Federal Trade Commis-
21 sion, shall submit to Congress recommendations—

22 (1) to identify requirements relating to security,
23 privacy, and notification in the case of a breach of
24 security or privacy, that should be applied to ven-
25 dors of personal health records with respect to infor-

1 mation in a personal health record offered or main-
2 tained by such vendor; and

3 (2) to determine which Federal government
4 agency is best equipped to enforce such requirements
5 recommended to be applied to such vendors of per-
6 sonal health records.

7 **SEC. 315. TEMPORARY BREACH NOTIFICATION REQUIRE-**
8 **MENT FOR VENDORS OF PERSONAL HEALTH**
9 **RECORDS.**

10 (a) IN GENERAL.—In accordance with subsection (b),
11 each vendor of personal health records shall, following the
12 discovery of a breach of security of individually identifiable
13 health information in such records maintained or offered
14 by such vendor—

15 (1) notify each individual who is a citizen or
16 resident of the United States whose individually
17 identifiable health information was acquired by an
18 unauthorized person as a result of such a breach of
19 security; and

20 (2) notify the Federal Trade Commission.

21 (b) APPLICATION OF REQUIREMENTS FOR TIMELI-
22 NESS, METHOD, AND CONTENT OF NOTIFICATIONS.—
23 Subsections (c), (d), (e), and (f) of section 302 shall apply
24 to a notification required under subsection (a) and a ven-
25 dor of personal health records, with respect to a breach

1 of security under such subsection (a) of individually identi-
2 fiable health information in such records maintained or
3 offered by such vendor, in the same manner that such sub-
4 sections apply to a notification required under such section
5 and a covered entity, with respect to a breach under such
6 section of protected health information held, used, or dis-
7 closed by such covered entity.

8 (c) NOTIFICATION OF THE SECRETARY OF HEALTH
9 AND HUMAN SERVICES.—Upon receipt of a notification
10 of a breach of security under subsection (a)(2), the Fed-
11 eral Trade Commission shall notify the Secretary of
12 Health and Human Services of such breach.

13 (d) ENFORCEMENT.—A violation of subsection (a)
14 shall be treated as an unfair and deceptive act or practice
15 in violation of a regulation under section 18(a)(1)(B) of
16 the Federal Trade Commission Act (15 U.S.C.
17 57a(a)(1)(B)) regarding unfair or deceptive acts or prac-
18 tices.

19 (e) EXEMPTION.—

20 (1) GENERAL EXEMPTION.—A vendor of per-
21 sonal health records shall be exempt from the re-
22 quirement under subsection (a) if, following a breach
23 of security, with respect to the individually identifi-
24 able health information of an individual in a per-
25 sonal health record, such vendor reasonably deter-

1 mines that there is no reasonable risk of substantial
2 harm, embarrassment, inconvenience, or unfairness to
3 the individual pursuant to such breach.

4 (2) PRESUMPTION OF NO REASONABLE RISK IN
5 CASES OF ENCRYPTION.—For purposes of paragraph
6 (1), the encryption of individually identifiable health
7 information of an individual in a personal health
8 record shall establish a presumption that no reason-
9 able risk of substantial harm, embarrassment, incon-
10 venience, or unfairness to the individual exists pur-
11 suant to a breach of security of such record. Any
12 such presumption may be rebutted by facts dem-
13 onstrating that the encryption has been or is reason-
14 ably likely to be compromised.

15 (3) FTC GUIDANCE.—Not later than 1 year
16 after the date of the enactment of this Act, the Fed-
17 eral Trade Commission shall issue guidance regard-
18 ing the application of the exemption in paragraph
19 (1).

20 (f) DEFINITIONS.—For purposes of this section:

21 (1) BREACH OF SECURITY.—The term “breach
22 of security” means, with respect to individually iden-
23 tifiable health information of an individual in a per-
24 sonal health record, acquisition of such information
25 without the authorization of the individual.

1 (2) INDIVIDUALLY IDENTIFIABLE HEALTH IN-
2 FORMATION.—The term “individually identifiable
3 health information” has the meaning given such
4 term in section 1171(6) of the Social Security Act
5 (42 U.S.C. 1320d(6)).

6 (g) EFFECTIVE DATE.—The provisions of this sec-
7 tion shall apply to breaches of security occurring during
8 the 2-year period beginning on the date of the enactment
9 of this Act.

10 **SEC. 316. BUSINESS ASSOCIATE CONTRACTS REQUIRED**
11 **FOR CERTAIN ENTITIES.**

12 Each organization, with respect to a covered entity,
13 that provides data transmission of protected health infor-
14 mation to such entity and that requires access on a routine
15 basis to such protected health information, such as a
16 Health Information Exchange, Regional Health Informa-
17 tion Organization, or E-prescribing Gateway, is required
18 to enter into a written contract (or other written arrange-
19 ment) described in section 164.502(e)(2) of title 45, Code
20 of Federal Regulations, with such entity and shall be
21 treated as a business associate of the covered entity for
22 purposes of section 111.

1 **SEC. 317. GUIDANCE ON IMPLEMENTATION SPECIFICATION**
2 **TO DE-IDENTIFY PROTECTED HEALTH INFOR-**
3 **MATION.**

4 Not later than 6 months after the date of the enact-
5 ment of this Act, the Secretary of Health and Human
6 Services shall issue guidance on how to best implement
7 the requirements for the de-identification of protected
8 health information under section 164.514(b) of title 45,
9 Code of Federal Regulations.

10 **SEC. 318. GAO REPORT ON TREATMENT DISCLOSURES.**

11 Not later than one year after the date of the enact-
12 ment of this Act, the Comptroller General of the United
13 States shall submit to Congress a report on the best prac-
14 tices related to the disclosure among health care providers
15 of protected health information of an individual for pur-
16 poses of treatment of such individual. Such report shall
17 include an examination of the best practices implemented
18 by States and by other entities, such as health information
19 exchanges and regional health information organizations,
20 including an examination of the extent to which such best
21 practices are successful with respect to the quality of the
22 resulting health care provided to the individual and with
23 respect to the ability of the health care provider to manage
24 such best practices.

1 **Subtitle C—Relationship to Other** 2 **Laws; Effective Date**

3 **SEC. 321. RELATIONSHIP TO OTHER LAWS.**

4 (a) APPLICATION OF HIPAA STATE PREEMPTION.—
5 Section 1178 of the Social Security Act (42 U.S.C. 1320d-
6 7) shall apply to a provision or requirement under this
7 title in the same manner that such section applies to a
8 provision or requirement under part C of title XI of such
9 Act.

10 (b) HEALTH INSURANCE PORTABILITY AND AC-
11 COUNTABILITY ACT.—The standards governing the pri-
12 vacy and security of individually identifiable health infor-
13 mation promulgated by the Secretary of Health and
14 Human Services under sections 262(a) and 264 of the
15 Health Insurance Portability and Accountability Act of
16 1996 shall remain in effect to the extent that they are
17 consistent with this title. The Secretary shall by rule
18 amend such Federal regulations as required to make such
19 regulations consistent with this title.

20 **SEC. 322. EFFECTIVE DATE.**

21 The provisions of this title (other than sections
22 301(c), 303, 314, 315, 317, and 318) shall take effect on
23 the date that is 12 months after the date of the enactment
24 of this Act.